

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

DATE OF SUMMARY PREPARATION: 18 July, 1997

COMPANY: Medical Packaging Corporation
941 Avenida Acaso
Camarillo, CA 93012-8700
Phone: 805-388-2383
Fax: 805-388-5531

CONTACT PERSON: Patricia V. Willis

DEVICE NAME: SNAP SWAB™
Culture Collection and Transport System

DEVICE CLASSIFICATION: Class I, General Controls

COMMON NAME: Microbiological specimen Culture
Collection and Transport device

PREDICATE DEVICE(S): CULTURE-PAK™ Collection and Transport System, Modified Stuart's Media (K932337/S1 and K936078), and CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media, K964637, CULTURE-PAK™ Collection and Transport System, Clinical Transport Media, K970597, Medical Packaging Corporation, Camarillo, CA.

Intended Use

Medical Packaging Corporation's SNAP SWAB™ Culture Collection and Transport System, with Modified Stuart's, Modified Amies, and Cary-Blair Transport Media is intended for use as a disposable, sterile culture Culture Collection device for use in the collection, preservation, and transportation of microbiological specimens.

Substantial Equivalence

Medical Packaging Corporation's SNAP SWAB™ Culture Collection and Transport System, available with Modified Stuart's, Modified Amies, and Cary-Blair Transport Media, is substantially equivalent to Medical Packaging Corporation's CULTURE-PAK™ Collection and Transport System, Modified Stuart's Media (K936078) and (K932337/S1), CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media, K964637, and CULTURE-PAK™ Collection and Transport System, Clinical Transport Media (K970597). Listed devices are intended to collect, preserve, and transport clinical specimens to the laboratory for microbiological analysis. Devices are composed of two plastic parts:

- The top plastic part of the *single swab* device holds 0.4 mL of transport media and a plastic shaft, Rayon® tipped swab. The top plastic part of the *dual swab* device holds 0.6 mL of transport media and two plastic shaft, Rayon® tipped swabs, and the top plastic part of the device with the Rayon® *Mini-Tip* swab holds 0.3 mL of transport media. The aluminum shaft, Rayon® *Mini-Tip* swab is for collection of either male urethral or nasopharyngeal specimens.
- The bottom plastic part of the device protects the swab(s) (*hereafter referred to as: Culture Collection device*) and fits tightly into the top plastic part. The SNAP SWAB™ Culture Collection and Transport System is packaged sterile. Sterilization is conducted at SteriGenics, International, Inc., and validated by North American Science Associates, Inc. for all configurations.

The methods for use are the same for the CULTURE-PAK™ Collection and Transport System, Modified Stuart's Media (K936078) and (K932337/S1), CULTURE-PAK™ Collection and Transport System, Modified Amies Transport Media, K964637, and CULTURE-PAK™ Collection and Transport System, with Clinical Transport Media, (K970597). The two plastic parts are pulled apart, exposing the swab(s). After the culture is collected, the bottom is refitted into the top. The media seal is broken and the fluid is forced into the bottom extrusion to keep the *Culture Collection device* moist for up to 72 hours at room temperature.

The primary similarities and differences between Medical Packaging Corporation's CULTURE-PAK™ Collection and Transport System, Modified Stuart's Transport Media, CULTURE-PAK™ Collection and Transport System, Modified Amies Media, CULTURE-PAK™ Collection and Transport System, Clinical Transport Media, *Cary-Blair Transport Media option*, and the SNAP SWAB™ Culture Collection and Transport System are the following: (1) The release of media from the cap through the hollow shaft of the SNAP SWAB™ is accomplished by breaking the

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SNAP SWAB™ Culture Collection and Transport System

swab shaft within the cap rather than breaking the plastic snap valve. The action required for breaking the swab and the snap valve are identical. Once the shaft is broken, the media flow through the shaft is identical to the **CULTURE-PAK™** device. (2) The **SNAP SWAB™** culture tube is individually labeled and is packaged 50 to a labeled foil pouch.

The **SNAP SWAB™ Culture Collection and Transport System** and the **CULTURE-PAK™ Collection and Transport System** have the same intended use. Like the **CULTURE-PAK™**, the **SNAP SWAB™** sealed hollow shaft is seated in the plug that holds the media in the top part of the device. The top is bent 45 ° to break the shaft allowing the media to flow through the exposed open shaft orifice into the bottom of the tube. The **SNAP SWAB™ Culture Collection and Transport System**, will also be available with two plastic shaft, Rayon® tipped swabs, and with an aluminum shaft Rayon® Mini-Tip (*Universal*) rayon swab.

All used materials should be treated as potentially infectious and bio-hazardous. Proper handling and disposal methods should be employed.

Patricia V. Willis Date: 7-18-97

Patricia V. Willis

Director, Customer Service and Regulatory Affairs



OCT - 8 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Patricia V. Willis
Director, Regulatory Affairs/
• Customer Service
Medical Packaging Corp.
941 Avendia Acasco
Camarillo, CA 93012

Re: K972726
Trade Name: Snap Swab Culture Collection and Transport System
Regulatory Class: I
Product Code: JSM
Dated: July 18, 1997
Received: July 21, 1997

Dear Ms. Willis:

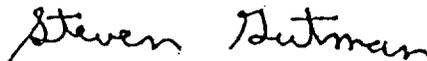
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in-vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Submission #K972726
SNAP SWAB Submission Revision • September 30, 1997
Medical Packaging Corporation

INDICATIONS FOR USE:

Medical Packaging Corporation's **SNAP SWAB™ Culture Collection and Transport System** is intended to be used for the collection, preservation, and transport of bacteriological specimens to the laboratory for evaluation. The media is intended to preserve the integrity of the specimen as well as minimize overgrowth of other organisms during transport.

Sean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number ~~K~~972726

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)